



MRI Breast Positioning System™

Instructions for Use



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IMPORTANT INFORMATION

The instructions in this document refer to the Domico MRI (Magnetic Resonance Imaging) Breast Positioning System™ with the following identification:

- **Manufacturer:** Domico Med-Device, LLC
- **Part Number:** 282
- **Product Name:** Domico MRI Breast Positioning System™
- **Type Designation:** Patient Positioning
- **Serial Number:** See Identification Tag
- **Manufacture Date:** See Identification Tag

Manufactured By

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Intended Use

The Domico MRI Breast Positioning System is to be used with the NeoCoil 16ch 1.5T/3T Breast Coil System.

Key Operational Characteristics

- Simple setup for optimal patient positioning
- Foam construction to provide comfort for patients

Safety Liability

Domico Med-Device, LLC assumes no liability for the safe and reliable operation of the Domico MRI Breast Positioning System being used other than its intended use as stated above.



WARNING!

To reduce risk of injury to user(s) and patient(s), user(s) must carefully read and understand this document

Patient Target Groups

Age, health, condition - No special limitations (The use of MRI system is limited, and the system manual should be reviewed).

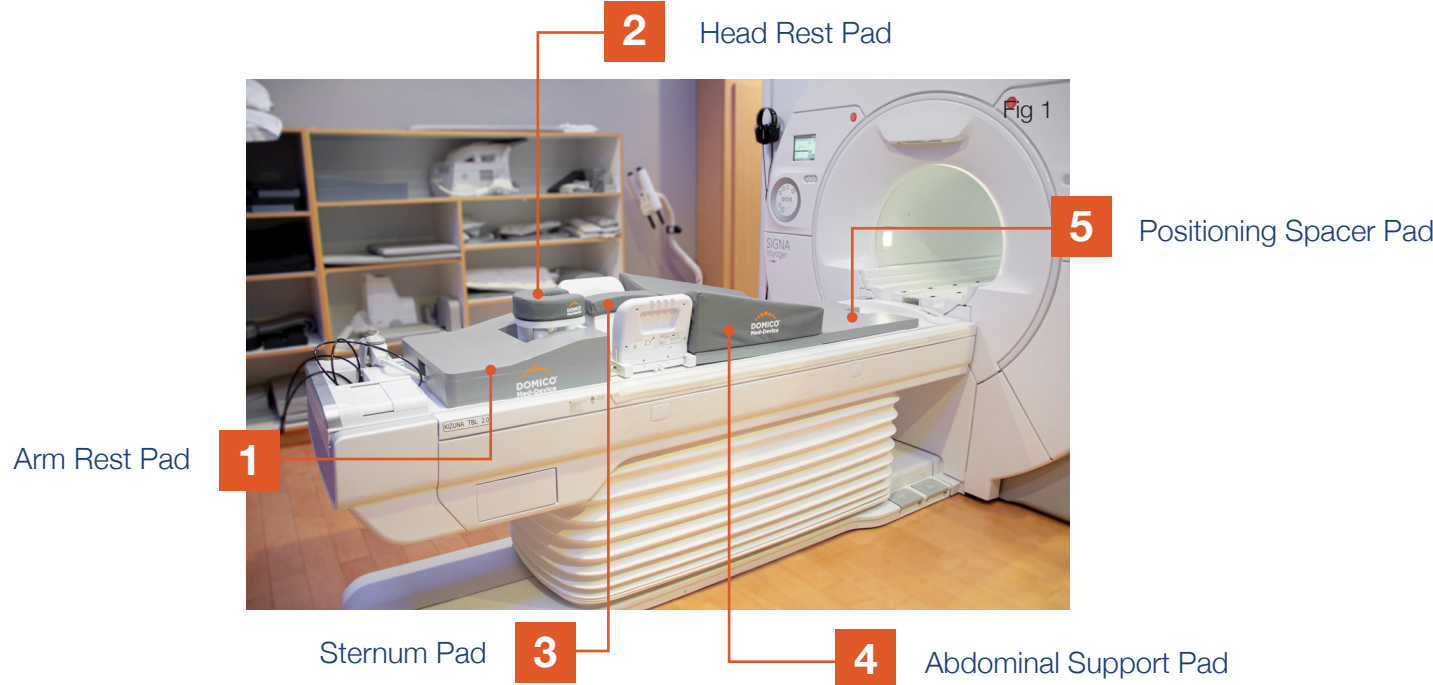
Product Lifetime

The MRI Breast Positioning System has a life expectancy of one year, assuming 20 scans per day, 300 use days per year, and 6,000 total cases per year.



System Overview

The MRI Breast Positioning System provides patient comfort and support for the arms, face, sternum, torso and lower extremities during imaging and biopsy procedures utilizing the NeoCoil 16ch Breast Coil. The pads promote natural spine alignment and place patients in an optimal position for procedures.



Item	Pad Component
1	Arm Rest Pad, Breast Coil
2	Head Rest Pad, Breast Coil
3	Sternum Pad(s), Breast Coil
4	Abdominal Support Pad, Breast Coil
5	Positioning Spacer Pad(s), Breast Coil

Pad Setup

1. Place the Arm Rest Pad on the table in front of the Head Rest. (Fig 1)



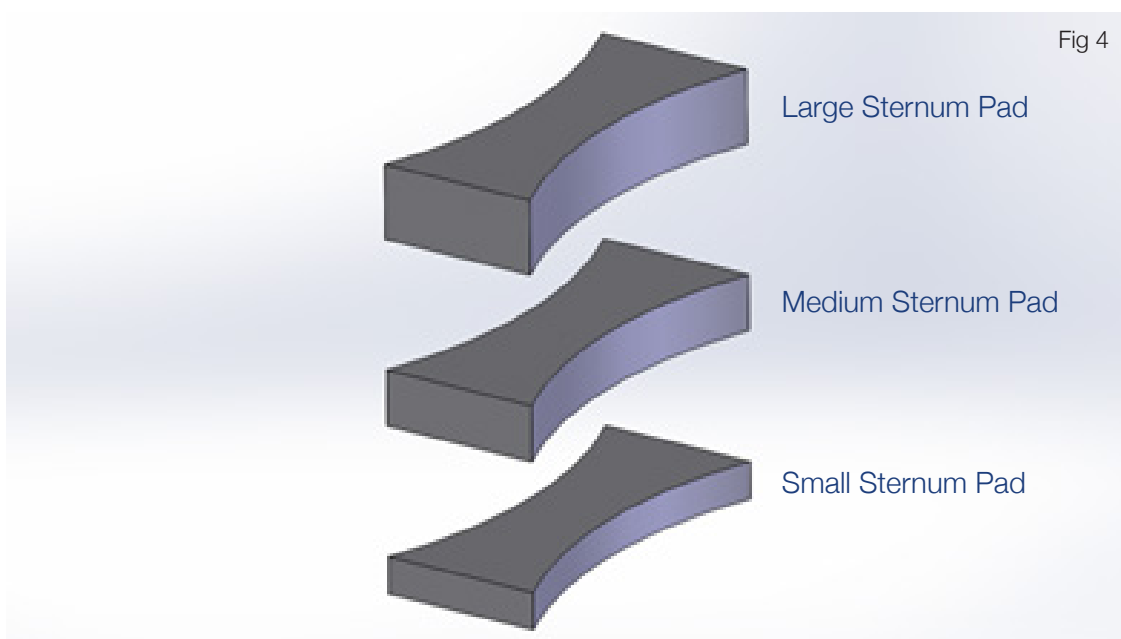
2. Attach Face Pad to the Head Rest superior to the Baseplate on the scanner table. (Fig 2)



3. Place the sternum pad on top of the Medial Array. (Fig 3).



4. Most patients find the medium pad to be the most comfortable, but depending on the patient's size and preference, the small, medium, or large pad will provide maximum comfort. (Fig 4).



5. Place the Abdominal Support Pad against the base of the breast coil. (Fig 5)



6. Use the Spacer pads for an extension of the lower legs or as a spacer pad underneath the abdomen/hip pad to reduce sternum pain and maintain natural spine alignment. (Fig 6)



Instruct the patient to lie face-down, placing their face on the provided face pad for comfort. You may optionally place a drape over the face pad to protect it from skin oils. Ensure the patient's chin does not rest on the headrest; when properly aligned, the patient should be able to see forward by looking down into the mirror integrated into the headrest.

Gently raise the patient's arms above their head and place them on the Arm Rest Pad to ensure both breasts are fully extended within their respective cavities for imaging. Position the patient's arms according to the patient's ability and comfort. The Arm Rest Pad must be used to separate the patient's hands, regardless of how the arms are positioned.



CAUTION!

To prevent patient looping and burns, the patient's hands should not contact each other, the patient's body, or the bore wall. Use pads to prevent these occurrences.

Pay special attention to ensuring the patient's comfort in the sternum area. If the patient experiences discomfort at the sternum, ask the patient to temporarily dismount from the coil. Then, slide a spacer pad under the abdominal pad. Once the spacer is in place, assist the patient in returning to their position on the coil to ensure a satisfactory comfort level is reached. If not, repeat the process with an additional spacer. Also update sternum pad size if required.



Other Useful Tips

Cleaning

Clean and disinfect in accordance with standard MRI room practices. Clean after use as follows:

- SANI-Cloth wipes.
- Rubbing alcohol (70% isopropyl alcohol).
- Soap & warm water.
- General-purpose soap or detergent cleaners.

Do Not Use:

- Rough or abrasive-faced sponges, brushes, cleaning pads, scrapers, or metal tools.
- Strong detergents or abrasives such as scouring powders.
- Excessively hot water or steam.

MRI Safety Information:

Part shall be safe to store or use in the presence of MRI equipment.

Warnings

- Do NOT use Pads if they show signs of damage like cracks, crazing, breaks, sharp edges, etc.
- DO NOT make any modifications to Pads, as they may compromise the safety of the device and may result in harm to the user or patient.
- DO NOT clean the Pads with cleaners other than those recommended, as the safety of the device may be impacted and may result in harm to the user or patient.

Warranty and Storage

Maintenance

Designed to be maintenance free, requiring only general cleaning throughout its life.

Limited Warranty

Domco Med-Device, LLC warrants to Customer that this product, manufactured by Domco Med-Device, LLC and sold to customer, will be free from defects in materials and workmanship for a period of one (1) year after delivery to Customer. This warranty shall not apply to any products which have been subjected to misuse, improper installation, alteration, neglect, accident, abnormal conditions of operation, or use under conditions other than those for which the products were designed.

EXCEPT FOR THE FOREGOING LIMITED WARRANTY, SELLER MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING ALL WARRANTIES OF FITNESS OR OF MERCHANTABILITY.

Disposal

Disposed of in an environmentally safe manner, per local governmental guidelines.